Meeting Minutes

Meeting Date:	June 30, 2025 at 2:00PM Eastern Time
Meeting Place:	Teleconference (Remote) Meeting is open to the public
Members in Attendance:	Noriea, Nicholas Rastein, Daniel Wang, Anthony Morland, Melissa Hawley, Robert Khan, Malika
Members Not in Attendance:	None
Guests:	None
Staff:	Hemmelgarn, Marian
Institution:	Thompson and Sjaarda, PA dba Retina Specialists

Call to Order: The meeting was called to order at Time 2:00PM. A quorum was present.

Conflicts of Interest: None declared by voting members of the IBC.

Meeting Minutes: Previous meeting minutes were reviewed and approved with no requested changes.

New Business:

PI:	Barañano, David MD, PhD
Sponsor:	AbbVie Inc
Protocol:	RGX-314-3101 A Randomized, Partially Masked, Controlled, Phase 3 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 Gene Therapy in Participants with nAMD (ASCENT)
	Barañano, David MD, PhD
Review Type:	Annual Review
NIH Guidelines:	III-C

Trial Summary: RGX-314-3101 (also known as M23-409) is a Phase 3, multi-center, partially masked, randomized, active-controlled, parallel arm study sponsored by AbbVie Inc and designed to investigate the efficacy and safety of the study agent ABBV-RGX-314 administered as a single subretinal injection in participants with neovascular age-related macular degeneration (nAMD). ABBV-RGX-314 (also known as RGX-314) is a recombinant adeno-associated viral vector (rAAV) serotype 8, containing a transgene that encodes for soluble anti-vascular endothelial growth factor (VEGF) antigen-binding fragment (Fab) protein.

Biosafety Containment Level per Risk Assessment: BSL-1 plus Standard Precautions

Comments:

- The Committee reviewed the Sponsor's study documents and the comprehensive study-specific Risk Assessment which provided a thorough description of the recombinant or synthetic nucleic acid molecules ("investigational product [IP]") and the proposed clinical research involving the IP.
    - The Committee agreed that the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial were well-described in the Risk Assessment.

- The Committee reviewed the Site's facility details, study-specific procedures and practices, training records, Annual Review Report and other applicable information provided by the Site for the purposes of the IBC review.
    - The Site verified that the information provided by the Chair was accurate.
    - The Site confirmed the accuracy of the Annual Review Report.
    - The Site confirmed that the storage location and the preparation/ administration location are in the same campus and the agent is walked from one location to the other.

Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions was passed by majority vote. There were no abstentions on voting.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

Reminder of IBC Approval Requirements.

Adjournment: Time 2:30PM

Post-Meeting Pre-Approval Note: None